IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE DIET DRUGS (Phentermine/ Fenfluramine/Dexfenfluramine) PRODUCTS LIABILITY LITIGATION	MDL Docket No. 1203
THIS DOCUMENT RELATES TO:	
SHEILA BROWN, et al. Plaintiffs,	
v.	CIVIL ACTION NO. 99-20593
AMERICAN HOME PRODUCTS CORPORATION, Defendant.	JURY TRIAL DEMANDED

FILED

THIRD AMENDED CLASS ACTION COMPLAINT

I. INTRODUCTION

1. Plaintiffs bring this action, pursuant to Rule 23 of the Federal Rules of Civil Procedure, on their own behalf and as representatives of a class of persons consisting of: All persons in the United States, its possessions and territories who ingested Pondimin and/or Redux ("Diet Drug Recipients"), or their estates, administrators or other legal representatives, heirs or beneficiaries ("Representative Claimants"), and any other persons asserting the right to sue AHP independently or derivatively by reason of their personal relationship with a Diet Drug Recipient, including without limitation, spouses, parents, children, dependents, other relatives or "significant others" ("Derivative Claimants"). The proposed class and subclasses do not include any claims

based upon a diagnosis by a qualified physician of primary pulmonary hypertension ("PPH") suffered by a Diet Drug Recipient.

2. Plaintiffs bring this action individually and as class and subclass representatives to recover damages, restitution, refunds, loss of consortium and/or for equitable, injunctive and declaratory relief against defendant American Home Products Corporation ("AHP"), which tested, labeled, manufactured, marketed, distributed, promoted and sold the diet drug Fenfluramine under the trade name "Pondimin" and the diet drug Dexfenfluramine under the trade name "Redux."

II. PARTIES

3. Plaintiff, Brenda Chambers is a resident and citizen of Washington, D.C. residing at 440 Burbank Street South, Washington, D.C. 20019. Plaintiff was prescribed, purchased and ingested Redux for approximately three weeks. Plaintiff Brenda Chambers has not been diagnosed as having mild or greater aortic valvular regurgitation or moderate or greater mitral valvular regurgitation (hereinafter "FDA Positive" regurgitation) by an echocardiogram, but may be at some increased risk for developing valvular heart disease as a proximate result of her ingestion of Redux.

4. Plaintiff, Donna Jarrell is a resident and citizen of the State of Pennsylvania, residing at 58 East Spring Avenue, Ardmore, PA 19003. Plaintiff was prescribed, purchased and ingested Pondimin for more than 60 days. Plaintiff Donna Jarrell has not been diagnosed as having FDA Positive levels of valvular regurgitation by an echocardiogram, but is at an increased risk for developing valvular heart disease as a proximate result of her ingestion of Pondimin.

5. Plaintiff, Vivian Naugle is a resident and citizen of the State of Pennsylvania residing at 329 N. Central Boulevard, Broomall, PA 19008. Plaintiff was prescribed, purchased

and ingested Pondimin for a period of 60 days or less. Plaintiff Vivian Naugle has been diagnosed by a qualified physician as having FDA Positive levels of valvular regurgitation by an echocardiogram which was performed on September 23, 1997. Plaintiff Vivian Naugle has moderate mitral insufficiency and mild aortic insufficiency.

6. Plaintiff, Quentin Layer is a resident and citizen of the State of Pennsylvania residing at 6455 Marsden Street, Philadelphia, PA 19135. Plaintiff was prescribed, purchased and ingested Redux for about eight months. Plaintiff Quentin Layer has been diagnosed by a qualified physician as having FDA Positive levels of valvular regurgitation by an echocardiogram which was performed on August 6, 1998. Plaintiff Quentin Layer suffers from mild aortic insufficiency and a thickened aortic valve.

7. Plaintiff, Joan S. Layer is the wife of plaintiff, Quentin Layer, and she resides with him at 6455 Marsden Street, Philadelphia, PA 19135. She is a resident and citizen of the State of Pennsylvania. She is a Derivative Claimant.

8. Plaintiff, Isabel Connor is a resident and citizen of the State of Pennsylvania. residing at 828 Elmwood Avenue, Sharon Hill, PA 19079. Plaintiff was prescribed, purchased and ingested both Pondimin and Redux. She ingested Pondimin from about February 1995 until about May 1996, and Redux from about August 1996 until about March 1997. Plaintiff Isabel Connor has had echocardiograms performed in November 1997, and in October 1999, which demonstrated that she has a physiologic condition of the Mitral valve of the heart which has resulted in mild mitral regurgitation. To date, plaintiff Isabel Connor has not been diagnosed by a qualified physician as having FDA positive levels of valvular regurgitation.

9. Defendant, American Home Products Corporation is a corporation organized and existing under and by virtue of the laws of the State of Delaware with its principal place of business at Five Giralda Farms, Madison, New Jersey 07940-0874.

10. At all times relevant hereto, defendant AHP was engaged in the business of marketing, distributing, promoting, testing, labeling and/or selling the pharmaceutical diet drugs Redux and Pondimin, by and through its subsidiaries and/or divisions, including Wyeth-Ayerst Laboratories Division, Wyeth-Ayerst Laboratories, Co., Wyeth-Ayerst Pharmaceuticals, Inc. and American Cyanamid Corporation. Defendant AHP's subsidiaries and/or divisions shall be referred to herein as "Wyeth", and any references to "Wyeth" in this complaint shall include defendant AHP.

11. Dexfenfluramine (Redux) is the d-isomer of Fenfluramine (Pondimin). From the standpoint of pharmacological method of action and effect, particularly the cardiotoxic effects which are the subject of this Complaint, the two drugs are indistinguishable.

12. AHP, and Wyeth do business in the State of Pennsylvania and in this judicial district. In fact, the majority of the activities of marketing, distributing, promoting, testing, labeling and/or selling of the diet drugs Redux and Pondimin occurred at defendant's Wyeth facilities, located in this judicial district in St. David's and Radnor, Pennsylvania.

III. JURISDICTION

13. This Court has jurisdiction over this civil action pursuant to 28 U.S.C. § 1332 and pursuant to the principles of supplemental jurisdiction. There is complete diversity of citizenship between each of the named plaintiffs and the defendant, and the amount in controversy exceeds $75,000.00, exclusive of interest and costs. Among other things, the amount in controversy

exceeds $75,000.00 exclusive of interest and costs because the Class has an undivided interest in obtaining injunctive/equitable relief that includes a comprehensive medical monitoring program and the creation of a medical research fund, the value of which exceeds $75,000, and because plaintiffs have claims for damages exceeding $75,000.00, exclusive of interest and costs.

IV. CLASS ACTION ALLEGATIONS

14. Plaintiffs bring this action, pursuant to Rule 23 of the Federal Rules of Civil Procedure, on their own behalf and as representatives of five Subclasses consisting of:

> All persons in the United States, its possessions and territories who ingested Pondimin and/or Redux ("Diet Drug Recipients"), or their estates, administrators or other legal representatives, heirs or beneficiaries ("Representative Claimants"), and any other persons asserting the right to sue AHP independently or derivatively by reason of their personal relationship with a Diet Drug Recipient, including without limitation, spouses, parents, children, dependents, other relatives or "significant others" ("Derivative Claimants"). The proposed class and subclasses do not include any claims based upon a diagnosis by a qualified physician of primary pulmonary hypertension ("PPH") suffered by a diet drug recipient.

15. Pursuant to Rule 23 of the Federal Rules of Civil Procedure, the following plaintiffs bring this action on behalf of the following subclasses.

> (A) Plaintiff Brenda Chambers brings this case individually and on behalf of "Subclass 1(a)", which consists of all Diet Drug Recipients (1) who ingested Pondimin and/or Redux for 60 days or less, and (2) who have not been diagnosed by a qualified physician as FDA Positive by an echocardiogram performed after the commencement of Diet Drug use but prior to September 30, 1999, and all Representative and Derivative Claimants in the class whose claims are based on their personal or legal relationship with a Diet Drug Recipient (1) who ingested Pondimin and/or Redux for 60 days or less, and (2) who has not been diagnosed by a qualified physician as FDA Positive by an echocardiogram performed after the commencement of Diet Drug use but before September 30, 1999.

(B) Plaintiff Donna Jarrell brings this case individually and on behalf of "Subclass 1(b)", which shall consist of all Diet Drug Recipients (1) who ingested Pondimin and/or Redux for more than 60 days, and (2) who have not been diagnosed by a qualified physician as FDA Positive by an echocardiogram performed after the commencement of Diet Drug use but prior to September 30, 1999, and all Representative and Derivative Claimants in the class whose claims are based on a personal or legal relationship with a Diet Drug Recipient (1) who ingested Pondimin and/or Redux for more than 60 days, and (2) who has not been diagnosed by a qualified physician as FDA Positive by an echocardiogram performed after the commencement of Diet Drug use but before September 30, 1999.

(C) Plaintiff Vivian Naugle brings this case individually and on behalf of "Subclass 2(a)", which shall consist of all Diet Drug Recipients (1) who ingested Pondimin and/or Redux for 60 days or less, and (2) who have been diagnosed by a qualified physician as FDA Positive by an echocardiogram which was performed after the commencement of Diet Drug use but prior to September 30, 1999, and all Representative and Derivative Claimants in the class whose claims are based on a personal or legal relationship with a Diet Drug Recipient (1) who ingested Pondimin and/or Redux for 60 days or less, and (2) who has been diagnosed by a qualified physician as FDA Positive by an echocardiogram which was performed after the commencement of Diet Drug use but before September 30, 1999.

(D) Plaintiffs Quentin Layer and Joan S. Layer bring this case individually and on behalf of "Subclass 2(b)", which shall consist of all Diet Drug Recipients (1) who ingested Pondimin and/or Redux for more than 60 days, and (2) who have been diagnosed by a qualified physician as FDA Positive by an echocardiogram which was performed after the commencement of Diet Drug use but prior to September 30, 1999, and all Representative and Derivative Claimants in the class whose claims are based on a personal or legal relationship with a Diet Drug Recipient (1) who ingested Pondimin and/or Redux for more than 60 days, and (2) who has been diagnosed by a qualified physician as FDA Positive by an echocardiogram which was performed after the commencement of Diet Drug use but before September 30, 1999.

(E) Plaintiff Isabel Connor brings this case individually and on behalf of "Subclass 3" (which may include persons also included in Subclasses 1(a) and 1(b)), which shall consist of all Diet Drug Recipients in the class who have been diagnosed by a qualified physician, after the commencement of Diet Drug use as having Mild Mitral Regurgitation but who have not been diagnosed by a qualified physician as FDA Positive by an echocardiogram performed after the commencement of Diet Drug use but prior to September 30, 1999, and all Representative and Derivative Claimants in the class whose claims are based on a personal or legal relationship with a Diet Drug Recipient who has been diagnosed by a qualified physician, after the commencement of Diet Drug use as having Mild Mitral Regurgitation but who has not been diagnosed by a qualified physician as FDA Positive by an echocardiogram performed after the commencement of Diet Drug use but before September 30, 1999.

16. Plaintiffs, the Class and each of the Subclasses bring this action for equitable, injunctive and declaratory relief pursuant to Federal Rule of Civil Procedure 23(b)(2) (with a right of opt-out) to create a Court-supervised fund to provide medical screening, medical services, medical research and education, and a medical/legal registry to assure that Diet Drug Recipients receive prompt and proper diagnosis and treatment of diet drug induced health problems.

17. Plaintiffs, the Class and each of the Subclasses, bring this action for compensatory and punitive damages pursuant to Federal Rule of Civil Procedure 23(b)(3). Diet Drug Recipients have suffered personal injury as a direct and proximate result of their ingestion of Pondimin and/or Redux, for which an award of damages is appropriate to them or their Representative Claimants. In addition, the Derivative Claimants have suffered damages as a direct and proximate result of the ingestion of Pondimin and/or Redux by the Diet Drug Recipients for which an award of damages is appropriate.

18. Plaintiffs, on behalf of themselves, the Class and each Subclass seek a refund of all amounts paid for their purchases of Pondimin and/or Redux.

19. The named plaintiffs herein are members of the Class and each Subclass they seek to represent. Plaintiff Brenda Chambers is a member of Subclass 1(a). Plaintiff Donna Jarrell is a member of Subclass 1(b). Plaintiff Vivian Naugle is a member of Subclass 2(a). Plaintiffs Quentin Layer and his wife, plaintiff Joan S. Layer, are members of Subclass 2(b). Plaintiff Isabel Connor is a member of Subclass 3.

20. The Class and each Subclass includes thousands of individuals, and therefore the members of the Class and Subclasses are each so numerous that joinder is impracticable.

21. There are questions of law and fact common to the class including, but not limited to:

a. whether defendant negligently labeled, distributed, promoted, tested, sold and/or marketed the drugs Redux and/or Pondimin;

b. whether the ingestion of Redux and/or Pondimin causes personal injuries, including valvular heart disease and cardiovascular injury;

c. whether the ingestion of Redux and/or Pondimin causes an increased risk of sustaining personal injuries including valvular heart disease and cardiovascular injury;

d. whether the increased risk of sustaining personal injuries including valvular heart disease and cardiovascular injury, that results from the ingestion of Redux and/or Pondimin makes periodic diagnostic and medical examinations, medical research and communications to the class effective and reasonably necessary;

e. whether the chemical composition and biological effects of Pondimin and/or Redux render those diet drugs toxic and/or unsafe for human ingestion;

f. whether AHP conducted adequate study, testing and analysis to determine whether and to what extent Pondimin and Redux were cardiotoxic;

g. whether AHP's post-marketing safety surveillance system was designed and implemented in a reasonable manner;

h. whether the labeling that accompanied Pondimin and/or Redux adequately warned of the adverse effects of the ingestion of Redux and/or Pondimin;

i. whether defendant AHP engaged in unconscionable, deceptive and/or unreasonable business practices and conduct;

j. whether defendant AHP knowingly, or intentionally concealed, suppressed or omitted material information intended to be relied upon by others in connection with the marketing, promotion, distribution and/or sale of Pondimin and/or Redux;

k. whether the class and the proposed subclasses have been injured by virtue of defendant AHP's negligence, recklessness, carelessness and/or unconscionable and/or deceptive business practices and conduct;

l. whether defendant AHP falsely and fraudulently misrepresented in its advertisements, promotional materials and other materials the safety, potential side effects, convenience, and efficacy of Pondimin and/or Redux;

m. whether defendant AHP knew or should have known that the ingestion of Pondimin and/or Redux leads to or poses a substantial increased risk of serious adverse health effects including but not limited to cardiovascular injury and/or valvular heart disease;

n. whether defendant AHP continued to label, manufacture, market, distribute, promote and sell Redux and/or Pondimin notwithstanding its knowledge of the dangerous nature of these diet drugs;

o. whether defendant AHP earned substantial profits as a result of its sale of diet drugs Redux and/or Pondimin; and

p. whether defendant AHP knowingly omitted, suppressed or concealed material facts about the unsafe and defective nature of Pondimin and/or Redux from government regulators, the medical community and/or the consuming public.

22. These and other questions of law and/or fact are common to the class and subclasses and predominate over any questions affecting only individual class members.

23. The claims of the named plaintiffs are typical of the claims of the respective Subclasses they seek to represent, in that each named plaintiff and all members of the proposed Subclasses ingested Pondimin and/or Redux and/or assert rights and claims as a "Derivative Claimant" or "Representative Claimant" as these terms are defined in the proposed class and subclass definitions.

24. In the case of the proposed Medical Monitoring Program, Medical Research and Education Fund and Medical/Legal Registry, the representative plaintiffs and the Subclass members as a whole will benefit from such relief, and their interests are aligned, because of the ingestion of Pondimin and/or Redux by the Diet Drug Recipients, and their consequential increased risk of contracting personal injuries, including valvular heart disease and/or related cardiopulmonary dysfunction. The diagnostic testing, research, collection of data and establishment of a Registry will work to benefit the entire class.

25. In the case of proposed Subclasses 2(a), 2(b) and 3, the representative plaintiffs for these subclasses who are Diet Drug Recipients, have been diagnosed by an echocardiogram as suffering from valvular regurgitation. They seek damages as a result of the injuries to their heart valves, the relief that any member of these proposed Subclasses will seek as a result of a similar diagnosis of valvular heart disease. In addition, the Derivative Claimant subclass representatives and subclass members have suffered a loss of consortium, love, services, and affection, and have incurred financial expenses and economic losses as a direct and proximate result of the personal injuries and damages suffered by their spouses who are Diet Drug Recipients. Thus, the pursuit of damages by these Subclass representatives for their injuries and losses will work to benefit the entire proposed Subclasses they seek to represent.

26. In the case of proposed Subclasses 1(a) and 1(b), there is a significant possibility that the Diet Drug Recipient representative plaintiffs may have suffered injury to the aortic and/or mitral valves of their hearts which will be revealed at such time as they have an echocardiogram. Therefore, they seek damages in the event that they receive an echocardiogram pursuant to any medical monitoring or surveillance program sought herein and such echocardiogram reveals that they have, in fact, suffered damage to their heart valves. In addition, in the event an echocardiogram reveals injury to the heart valves of any Diet Drug Recipient, the Derivative Claimants seek an award of damages for the loss of consortium, love, services and affection they suffered and the financial and economic expenses they incurred as a direct and proximate cause of the injuries to the heart valves sustained by the Diet Drug Recipients as to whom they assert a derivative claim. Thus, the pursuit of relief by these subclass representatives benefits the class as a whole.

27. In the case of proposed Subclass 3, plaintiff Isabel Connor has a physiologic condition of the Mitral valve of the heart which produced mild regurgitation, but she has not been diagnosed by a qualified physician as having an FDA positive level of valvular regurgitation. Nevertheless, this Subclass representative seeks damages for the physiologic condition of her mitral valve of her heart, and her pursuit of damages for that claim will work to benefit the entire proposed Subclass 3. In addition, Derivative Claimants to Subclass 3 members have suffered a loss of consortium, love, services, affection and has incurred financial expenses and economic losses as a direct and proximate result of the damages and personal injuries suffered by the Diet Drug Recipient to their mitral heart valves as a result of their ingestion of Pondimin and/or Redux. Thus, the pursuit of relief by the Subclass 3 class representative will work to benefit the entire proposed Subclass 3.

28. Finally, all representative plaintiffs seek a refund of and restitution for monies paid as a result of their purchases of Pondimin and/or Redux, all of which occurred as a result of defendant AHP's wrongful and improper conduct in connection with the manufacturing, marketing, distribution, testing, promotion, labeling and/or selling of the diet drugs Pondimin and/or Redux. All plaintiffs therefore seek to disgorge defendant AHP of the monies inappropriately acquired by it as a result of the sale of Pondimin and/or Redux.

29. Plaintiffs will fairly and adequately represent and protect the interests of the members of the Subclass they represent. Each of the representative plaintiffs have retained counsel competent and experienced in complex class actions and products liability litigation to represent them and the members of the proposed Subclasses. Accordingly, the interests of each Subclass will be adequately protected and advanced. In addition, there is no conflict of interest

between the representatives of the proposed Subclasses and the members of the respective Subclasses. The interests of all class representatives are aligned because they have a strong interest in obtaining the requested medical monitoring diagnostic testing and the creation of the Medical Research and Education Fund and the creation of the Medical/Legal Registry. There is a strong common interest in the collection of medical data and research into the cause and treatment of the illnesses caused by the ingestion of Pondimin and/or Redux. In addition, the members of all the classes have an interest in securing their right to compensatory damages as a consequence of any injuries caused by Pondimin and/or Redux whether ascertained through an equitable monitoring program or not. Finally, each of the proposed Subclasses is represented by a separate class representative and Subclass counsel, to assure that the rights of the members of each proposed Subclass will be protected by an independent advocate without a conflict of interest.

30. Notice can be provided to class members by a combination of published notice and first class mail using techniques and forms of notice similar to those customarily used in drug-related product liability cases and complex class actions.

31. The plaintiffs, on behalf of each Class and Subclass, seek equitable relief in the form of a Court-ordered and supervised medical monitoring program, funded by defendant, to assist plaintiffs and the class members in the detection and treatment of valvular heart disease. Such a program would include the following:

a. A method to notify individuals who ingested Redux and/or Pondimin of the increased risk of harm that they have suffered as a result of the ingestion of these diet drugs;

b. Provision for the accumulation and analysis of relevant medical and demographic information from class members including, but not limited to, the results of echocardiograms performed on class members as part of a Medical Research and Education Fund;

c. Provision for the creation, maintenance and operation of a Medical Registry in which relevant demographic and medical information concerning all class members is gathered, maintained and analyzed;

d. Provision for medical research concerning the incidence, prevalence, natural course and history, diagnosis and treatment of diet drug induced personal injury, including, *inter alia*, valvular heart disease; and

e. Publication of and other dissemination of all such information to members of the class and their physicians.

32. All plaintiffs in Subclass 1(b) seek equitable relief in the form of a Court-ordered and supervised monitoring program, funded by defendant, to assist plaintiffs and the class members in the early detection of valvular heart disease including, but not limited to, the creation of a Court-supervised fund to provide Diet Drug Recipient members of Subclass 1(b) with an echocardiogram and associated interpretive physician visit to determine whether and to what extent valvular heart disease is present in such persons.

33. Plaintiffs on behalf of Subclasses 1(a), 1(b), 2(a), 2(b) and 3 seek equitable relief in the form of a Court ordered and supervised monitoring program, funded by defendant which would include ongoing testing and monitoring of individuals who ingested Redux and/or Pondimin in order to determine whether any FDA positive levels of valvular regurgitation, which are present in Diet Drug Recipient individuals, are progressing in severity and requires further treatment.

34. Class certification with respect to plaintiffs' claims for relief in the form of the creation of a Court-supervised fund to provide medical research, education, monitoring and screening is appropriate pursuant to Fed.R.Civ.P. 23(a) and 23(b)(2) because defendant has acted, or refused to act, on grounds generally applicable to the class, making appropriate preliminary and final injunctive and declaratory relief consisting of medical monitoring and notice with respect to plaintiffs and the class members.

35. Certification of Subclasses 1(a), 1(b), 2(a), 2(b) and 3 is appropriate pursuant to Fed.R.Civ.P. 23(a) and 23(b)(3), because the questions of law and fact common to the members of these Subclasses predominate over any questions affecting only individual members. This class action is superior to other available remedies for the fair and efficient adjudication of this controversy.

V. FACTUAL BACKGROUND

36. At all times relevant, defendant manufactured, created, designed, tested, labeled, sterilized, packaged, distributed, supplied, marketed, sold, advertised, and otherwise distributed in interstate commerce, the drug dexfenfluramine under the brand name Redux, and the drug fenfluramine under the brand name Pondimin.

37. At all times relevant, defendant failed to conduct adequate and appropriate studies which would have revealed that Pondimin and Redux created a high risk of valvular heart disease and failed to provide any warnings concerning this risk.

38. To begin with, both Fenfluramine and its d-isomer, Dexfenfluramine, are serotonin reuptake inhibitors which affect circulating blood levels of serotonin. This was clearly known to AHP.

39. The medical literature demonstrates that other drugs such as ergotamines and Methysergide and diseases such as Carcinoid Syndrome which likewise effect serotonin blood levels are causally associated with valvular heart disease of the type caused by Dexfenfluramine and Fenfluramine.

40. In addition, it was reported as early as 1964 that Fenfluramine is cardiotoxic.

41. Moreover, as early as 1977 researchers postulated that Fenfluramine could cause heart valve lesions.

42. Despite the facts set forth above, which AHP should have been aware of, there is no evidence that AHP ever conducted or sponsored any animal or clinical studies that were designed or intended to investigate the potential relationship between Pondimin and/or Dexfenfluramine and valvular heart disease, prior to withdrawal of the drugs from the market.

43. Despite the facts set forth above, prior to July, 1997, AHP did not advise prescribing physicians or the consuming public that there was a potential relationship between the use of Pondimin or Redux and valvular heart disease.

44. The Investigational New Drug Application submitted to the United States Food and Drug Administration for Redux contained a carcinogenicity study regarding the effects of Fenfluramine isomers administered to the Fisher rat. It was reported that the study had been completed on September 19, 1990, with the complete assembly of the file in March 1992. One of the findings in the study was that focal fibrosis was more common in the hearts of rats who received treatment with Fenfluramine isomers than in untreated controls.

45. Despite this report, AHP did not examine the heart tissue which was the subject of the Fisher rat study which was available for such examination. Such an examination would have

revealed a significant increase in fibrosis and valvular heart damage in the hearts of rats treated with Fenfluramine isomers as compared with untreated controls.

46. AHP did not perform or require further animal testing in light of the reports of focal fibrosis in the hearts of rats treated with Fenfluramine isomers.

47. Despite the findings in the Fisher rat study, AHP failed to include any information concerning the potential relationship between Fenfluramine and/or Dexfenfluramine and heart lesions in either animals or human beings in the labeling for Pondimin or Redux through July of 1997.

48. During the period from 1994 through March of 1997, AHP, through its Wyeth Ayerst Laboratory Division, received at least thirty separate reports concerning patients who had taken FenPhen and sustained cardiac valvulopathy as determined by auscultation and/or echocardiogram.

49. Many of the reports of valvular heart disease ("VHD") which were received by the Wyeth Ayerst Laboratory Division of AHP were reported to the company in clusters during 1994 and 1995.

50. AHP made no attempt to contact either the physicians or patients involved in the thirty reports of valvular heart disease associated with Fenfluramine use which the company received in the period from 1994 through 1996.

51. Despite these reports of VHD, AHP failed to conduct any animal study, clinical investigation, or other inquiry concerning the potential relationship between the use of Fenfluramine isomers and valvular heart disease and did not provide any warning to physicians

and patients of the potential relationship between valvular heart disease and Fenfluramine/Dexfenfluramine until July of 1997.

52. Under federal regulations, AHP was legally obligated to report serious and unexpected adverse drug reactions to the FDA within fifteen days of learning of such reactions.

53. During the period from 1994 through at least July of 1997, valvular heart disease was not labeled as an adverse reaction associated with Pondimin or Redux. Therefore, for regulatory purposes, it represented a serious "unexpected" adverse reaction which should have been reported as such to the FDA within the prescribed fifteen day time frame.

54. Nevertheless, AHP failed to report to the FDA many of the instances of valvular heart disease in Fenfluramine users identified to it during the period from 1994 through 1996 as serious, unexpected adverse reactions.

55. AHP, through its Wyeth Ayerst Laboratory Division, failed to identify valvular heart disease as an adverse reaction associated with the use of Pondimin and/or Redux until after it received reports of such an association from the Mayo Clinic in 1997 and learned that the Mayo Clinic intended to bring these reports to the attention of the public and federal regulators.

56. During the period from 1990 through the spring of 1997, AHP failed to examine the information concerning reports of adverse reactions which were available in its computer database to determine whether its labeling for Pondimin should be revised to reflect reported adverse reactions in that period.

57. The system which AHP used to receive, record, and report adverse events involving Pondimin did not meet the requirements of the FDA or contemporary standards of good pharmaceutical company practice.

58. Specifically, a Wyeth Ayerst internal memo dated July 9, 1996, concluded that the company's Worldwide Safety Surveillance System was below contemporary standards of practice in that, among other things, (a) the medical doctors who reviewed and classified adverse events for the company were also involved in direct support of U.S. marketing, thereby creating a conflict of interest, (b) the company did not have sufficient resources dedicated to safety surveillance activities, and (c) the company did not have up to date computer systems to perform safety surveillance activities.

59. Moreover, an audit report issued by the FDA to Wyeth Ayerst Laboratories in Radnor, Pennsylvania, cited the company for the following:

> "I. The Adverse Event Reporting System (of Wyeth Ayerst) failed to assure that all reports were accurate and submitted within required time frames ... [and]
>
> II. [There is a] lack of assurance that all [Wyeth] personnel active in the initiation processing and reporting of ADE [adverse drug events] are qualified to perform the duties assigned to them...."

60. On April 9, 1996, B. Taylor Thompson, M.D., a Professor of Medicine at the Harvard Medical School practicing in the Pulmonary & Critical Care Unit at the Massachusetts General Hospital reported the results of his review of 32 cases of pulmonary hypertension in patients who had used Dexfenfluramine to Interneuron which passed on this report to the FDA. It was customary practice for such reports to have been provided to AHP.

61. Dr. Thompson concluded that 16 of the 32 cases did not represent "primary" pulmonary hypertension. Rather, he concluded that these 16 cases represented pulmonary hypertension which was secondary to "left heart failure, [and] valvular heart disease...." The

FDA, upon reviewing this report concluded that "this analysis raises the further issue that Dexfenfluramine may potentiate causes of secondary pulmonary hypertension . . ."

62. Therefore, AHP was on notice that the use of Dexfenfluramine was associated with significant adverse left heart disease including mitral and aortic valvular insufficiency.

63. Nonetheless, AHP failed to initiate any animal studies or clinical investigations to determine the nature and extent of this relationship and failed to provide any warning concerning the relationship between the use of Fenfluramine isomers and the development of valvular heart disease until this relationship was brought to the public's attention by the Mayo Clinic's researchers in July of 1997.

64. Based on the above findings, there is substantial evidence to support the conclusion that AHP was negligent in failing to ascertain and report the existence, nature, and extent of the risk of valvular heart disease posed by Fenfluramine and Dexfenfluramine which were marketed for use by over six million human beings within the United States.

65. There is also substantial evidence that the significant risk of valvular heart disease posed by Fenfluramine and Dexfenfluramine outweighs any benefit afforded by these drugs.

66. According to FDA officials in the CDER's Division of Metabolic and Endocrinologic Drug Products who reviewed the NDA for Redux, studies on the effectiveness of Dexfenfluramine submitted in the NDA did not demonstrate a mean 5 percent weight loss over 12 months even though that is the standard of effectiveness which the FDA believed that weight loss drugs should meet.

67. In addition, no adequate or well-controlled study has ever demonstrated that Fenfluramine or Dexfenfluramine ameliorate the co-morbidities commonly associated with obesity,

and data showing that long term weight reduction alone reduces mortality (without a reduction in co-morbidities) is scarce. On the contrary, findings suggest that prevention of severe obesity may be more generally effective in reducing obesity-related mortality in the U.S. population.

68. Finally, no studies demonstrate that the use of Fenfluramine and Dexfenfluramine brings about a long term reduction in weight after discontinuing use of the drug. To the contrary, in one study, discontinuing use of Fenfluramine was found to result in more rapid regaining of weight than regaining with behavior therapy alone, and adding pharmacotherapy to behavior therapy apparently compromised the long term effects of the latter treatment.

69. Indeed, the only way these drugs work is if they are taken indefinitely, yet indefinite use poses an absolute safety threat.

70. Because Dexfenfluramine and Fenfluramine are ineffective for their intended use and because use of these drugs produces enormous risk of VHD as well as life-threatening complications such as primary pulmonary hypertension, no reasonable pharmaceutical company exercising due care would have marketed these drugs.

71. Indeed, when evidence concerning the risk of VHD associated with Fenfluramine isomers was disclosed to the public and the FDA in the Summer of 1997, both drugs were rapidly withdrawn from the market.

72. Following that, numerous clinical and epidemiologic studies reported results showing that there was statistically significant and large increased risk of valvular heart disease associated with the use of Pondimin and Redux.

VI. PLAINTIFFS' CAUSES OF ACTION

COUNT I

NEGLIGENCE

73. Plaintiffs incorporate by reference all other paragraphs of this complaint as if fully set forth here and further alleges as follows.

74. Defendant is the manufacturer, seller, and/or supplier of the drugs Redux and Pondimin.

75. Redux and Pondimin were not accompanied by any warnings regarding the significant risk of valvular heart disease associated with the ingestion of Pondimin and Redux. The warnings given by defendant did not accurately reflect the existence of the risk let alone the incidence, symptoms, scope or severity of such injuries.

76. Defendant failed to perform adequate testing concerning the safety of the drugs Redux and Pondimin in that adequate testing would have shown that Redux and Pondimin pose a serious risk of valvular heart diseases which would have permitted adequate and appropriate warnings to have been given by defendant to prescribing physicians and the consuming public.

77. Defendant failed to effectively warn users and physicians that numerous other methods of weight loss, including non-drug methods of weight loss such as diet control and exercise, should be the first line and/or exclusive methods of weight loss, particularly for non-clinically obese individuals and for high risk individuals.

78. Defendant had a duty to exercise reasonable care in the manufacture, sale and/or distribution of the drugs Redux and Pondimin, including a duty to assure that the products did not

cause users to suffer from unreasonable, dangerous side effects when used alone or in foreseeable combination with other drugs.

79. Defendant was negligent in the design, manufacture, testing, advertising, marketing, promotion, labeling, warnings given, and sale of Redux and Pondimin in that, among other things, it:

a. Failed to accompany the product with proper warnings regarding all possible adverse side effects associated with the use of Redux and Pondimin;

b. Failed to conduct adequate pre-clinical and clinical testing and post-marketing surveillance to determine the safety of the drugs Redux and Pondimin;

c. Failed to provide adequate training and instruction to medical care providers for appropriate use of the drugs Redux and Pondimin;

d. Failed to warn plaintiffs and the class, prior to actively encouraging the sale of Redux and Pondimin, either directly or indirectly, orally or in writing, about the following: (1) the need for comprehensive, regular medical monitoring to ensure early discovery of potentially fatal pulmonary and cardiac side effects; (2) the possibility of becoming disabled as a result of the drug use and/or having to undergo heart surgery in order to correct resultant valvular heart defects; (3) that such surgery may leave an unsightly scar or scars; or (4) that heart procedures, heart defects and/or cardiopulmonary injuries may become protracted, debilitating, difficult, and painful, necessitating lengthy surgery and/or several visits to the doctor, clinic or hospital;

e. Failed to warn that the risks associated with Redux and Pondimin would exceed the risks of other comparable forms of weight loss;

f. Failed to effectively warn about the increased danger and unapproved status of combination use of Redux and/or Pondimin and phentermine;

g. Negligently marketed Pondimin and Redux despite the fact that the risks of the drug were so high and the benefits of the drugs were so speculative that no reasonable pharmaceutical company, exercising due care, would have done so.

h. Recklessly, falsely and/or deceptively represented or knowingly omitted, suppressed or concealed facts of such materiality regarding the safety and efficacy of Pondimin and Redux to or from the FDA and/or the FDA's Advisory Committee, that had the FDA or its Advisory Committee members known of such facts, that the diet drug Redux and Pondimin would never have been approved and no physician would have been able to prescribe these diet drugs to plaintiffs or to members of the class;

i. Remained silent despite its knowledge of the growing public acceptance of misinformation and misrepresentations regarding both the safety and efficacy of the ingestion of Pondimin and Redux, and did so because the prospect of huge profits outweighed health and safety issues, all to the significant detriment of plaintiffs and the class;

j. Failed to perform its post-manufacturing duty to warn which arose when it knew, or with reasonable care should have known, that its diet drugs were being prescribed in a deadly or injurious combination or manner;

k. Was otherwise careless, negligent, grossly negligent, reckless and acted with willful and wanton disregard for the rights of plaintiffs and the class.

80. Despite the fact that defendant knew or should have known that Redux and Pondimin caused unreasonable, dangerous side effects which many users would be unable to

remedy by any means, defendant continued to market Redux and Pondimin to consumers, including Plaintiffs and the class, when there were safer alternative methods of weight loss.

81. Defendant knew or should have known that consumers such as plaintiffs and the class would foreseeably suffer injury as a result of defendant's failure to exercise ordinary care as described above.

82. Defendant's actions as described herein constitute knowing omissions, suppression or concealment of material facts, made with the intent that others rely upon such concealment, suppression or omissions in connection with the marketing of Pondimin and/or Redux.

83. The behavior of defendant described herein demonstrates that defendant acted unlawfully and negligently, used or employed unconscionable commercial and business practices, engaged in deception, fraud, false pretenses, false promises or misrepresentations, and/or perpetrated the knowing concealment, suppression or omission of material facts with the intent that consumers, including plaintiffs and the class, rely upon such concealment, suppression or omission, in connection with the sale or advertisement of Pondimin and Redux.

84. As the direct and proximate cause and legal result of the defendant's failure to supply appropriate warnings for the drugs Redux and Pondimin, and as a direct and legal result of the negligence, carelessness, other wrongdoing and actions of defendant described herein, the Diet Drug Recipient plaintiffs and the class have ingested Redux and/or Pondimin, and have suffered a significantly increased risk of valvular heart disease and/or related cardiopulmonary dysfunction for which medical monitoring, in the form requested herein, is necessary, appropriate and beneficial.

85. Defendant's negligence was a proximate cause of the increased risk of harm suffered by the Diet Drug Recipient plaintiffs and the plaintiff class as previously set forth herein, and the personal injury damages and other losses suffered by the representatives of and members of each Subclass.

86. As a direct and proximate cause and legal result of the defendant's negligence, carelessness, and the other wrongdoing and actions of defendant as described herein, the Derivative Claimants and class member Derivative Claimants have suffered a loss of consortium, services, love and affection, and have incurred financial expenses and have suffered economic losses.

VII. INJUNCTION AND EQUITABLE RELIEF

MEDICAL MONITORING

87. Plaintiffs incorporate by reference all other paragraphs of this complaint as if fully set forth here and further allege as follows on behalf of themselves and all others similarly situated:

88. As a direct and proximate result of defendant's acts, omissions, and conduct as set forth above, the Diet Drug Recipient plaintiffs and each class member of the proposed class who have ingested Pondimin and/or Redux have been exposed to a hazardous substance and suffered a significantly increased risk of contracting serious injury or latent disease, including valvular disease and cardiovascular heart dysfunction. This increased risk makes periodic diagnostic and medical examinations reasonable and necessary.

89. Early detection and diagnosis of these diseases is clinically invaluable since it can prevent, reduce and/or significantly delay resulting discomfort, suffering and/or death and since these conditions can often appear asymptomatic absent proper testing.

90. Easily administered, cost-effective monitoring and testing procedures exist which make the early detection and treatment of such injuries or diseases possible and beneficial. For example, administration of several available non-invasive tests can readily diagnose the presence and extent of valvular heart disease, even in asymptomatic individuals. Early diagnosis of these diseases and conditions will allow prompt and effective treatment which will reduce the risk of morbidity and mortality which these patients would suffer if treatment was delayed until their conditions became overtly symptomatic.

91. Diet Drug Recipient plaintiffs and the proposed class members who ingested Pondimin and/or Redux are at risk for valvular heart disease and/or other cardiopulmonary injury.

92. By virtue of their exposure to diet drugs, the Diet Drug Recipient plaintiffs and the members of the class who ingested Pondimin and/or Redux are at an increased risk for developing a form of valvular heart disease, the natural course and history of which is uncertain. Accordingly, medical, scientific and epidemiologic research is reasonably necessary for the diagnosis and treatment of such disease.

93. The increased susceptibility to injuries and irreparable threat to the health of Diet Drug Recipient plaintiffs and the class members resulting from their ingestion of Redux and/or Pondimin can be mitigated or addressed by the creation of a comprehensive medical monitoring program that:

a. Notifies individuals who ingested Redux and/or Pondimin of the potential harm from Redux and/or Pondimin;

b. Aides them in the early diagnosis and treatment of resulting injuries through ongoing testing and monitoring of Redux and Pondimin;

c. Provides for state-of-the-art echocardiograms for members of the class;

d. Provides for accumulation and analysis of relevant medical and demographic information from class members including, but not limited to the results of echocardiograms performed on class members;

e. Provides for the creation, maintenance, and operation of a "registry" in which relevant demographic and medical information concerning all class members is gathered, maintained, and analyzed;

f. Provides for medical research concerning the incidence, prevalence, natural course and history, diagnosis and treatment of diet drug induced valvular heart disease; and

g. Publishes and otherwise disseminates all such information to members of the class and their physicians.

94. Class member users of Redux and/or Pondimin have no adequate remedy at law in that monetary damages alone will not compensate them for the continuing nature of the harm to them, and a monitoring program which notifies them of possible injury and aids in their treatment can prevent the greater harms which may not occur immediately and which may be preventable if the health risks are diagnosed and treated before they occur or become worse.

95. Without a court-approved medical monitoring program, Redux and Pondimin users may not receive prompt medical care which could detect and prolong their productive lives, increase prospects for improvement and minimize disability.

VIII. DAMAGES RELIEF FOR PROPOSED SUBCLASSES

96. Plaintiffs incorporate by reference all other paragraphs of this complaint as if fully set forth herein and further allege on behalf of themselves and all others similarly situated:

97. As a direct and proximate result of defendant's acts, omissions and conduct as set forth above, the Diet Drug Recipient plaintiffs and each class member was exposed to a hazardous substance; members of Subclasses 1(a) and 1(b) may have suffered, and members of Subclass 2(a), 2(b) and 3 have suffered personal injury in the form of valvular heart disease and/ or other cardiovascular heart dysfunction. Plaintiffs therefore request an award of damages to fully compensate them for the injuries sustained, including, *inter alia*, an award of damages for defendant's negligence to include compensation for all damages and losses, and for loss of consortium.

IX. REFUND/RESTITUTION RELIEF FOR ALL CLASS MEMBERS

98. Plaintiffs incorporate by reference all other paragraphs of this complaint as if fully set forth herein, and further allege on behalf of themselves and all class members that as a direct and proximate result of defendant's acts, omissions and conduct as set forth above, plaintiffs, and each class member of the entire class are entitled to an award of a refund, restitution and incidental economic losses, including the purchase price paid by class members in connection with their purchases of the diet drugs Pondimin and/or Redux, similar to such relief as is sought in the pending case *Bradley, et al. v. American Home Products Corporation*, Docket No. MID-L-___-99

(proposed nationwide class, excluding citizens of New Jersey, brought under New Jersey Consumer Fraud Act, N.J.S.A. 56:8-1 *et. seq.*, seeking, *inter alia*, refund and restitution reliefs).

X. PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for relief as follows:

A. That this action be certified as a class action on behalf of the proposed nationwide class and subclasses described herein, *i.e.*, certification of the class and proposed Subclasses 1(a), 1(b), 2(a), 2(b) and (3);

B. That a comprehensive court supervised Medical Monitoring Program be created as proposed herein, to assure the early diagnosis and treatment of cardiovascular and pulmonary injuries resulting from the ingestion of Redux and/or Pondimin, that will provide ongoing testing and monitoring, a Medical Research and Education Fund and a Medical/Legal Registry, to be implemented in a manner that meets all legal requirements and assures the appropriate participation of various state courts which have certified or conditionally certified state-wide classes for medical monitoring relief involving Pondimin and Redux, *e.g.*, New Jersey (*Vadino, et al. v. AHP*, Docket No. MID-L-425-98) (statewide Unfair and Deceptive Acts and Practices and medical monitoring class);

C. That an award of personal injury damages and loss of consortium damages be made to members of the Class:

D. That the Court enter an Order requiring defendant AHP to refund all monies acquired by means of the above practices, namely, ordering that AHP refund and make restitution of all monies acquired from the sales of Pondimin and Redux to plaintiffs and the proposed Subclass members; and

E. That an award of attorneys' fees, expenses, and costs of this action and any other relief to which the plaintiffs are entitled be made in favor of plaintiffs and the class.

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Dated: May 2, 2000

CERTIFICATE OF SERVICE

The undersigned certifies that on May 2, 2000, a true and correct copy of the Third Amended Class Action Complaint was served via First Class Mail, postage prepaid to All Counsel on the attached list.

ARNOLD LEVIN, ESQUIRE

RE: In re: Diet Drugs Products Liability Litigation -- MDL No. 1203

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